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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/662,812 | 09/15/2000 | Andrew D. Murdin | 032931/0235 | 1714 |

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| EXAMINER |
|---|
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| ART UNIT | PAPER NUMBER |
|---|---|
| 1645 | 9 |

DATE MAILED: 07/01/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

| Application No. | Applicant(s) |
|---|---|
| 09/662,812 | Murden et al |
| **Examiner** | **Art Unit** |
| Portner | 1645 |

*-- Th MAILING DATE of this communication appears on the c ver sh et with the c rrespondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1) ☒ Responsive to communication(s) filed on *Sep 15, 2000*

2a) ☐ This action is **FINAL.** 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

**Disposition of Claims**

4) ☒ Claim(s) *1-37* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☐ Claim(s) _____ is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☒ Claims *1-37* are subject to restriction and/or election requirement.

**Application Papers**

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

**DETAILED ACTION**

Claims 1-37 are pending

***Election/Restriction***

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-14, 19, 35 and 36 are, drawn to DNA, vector, host cell, probes, primers, classified in class 536, subclass 23.1.

II. Claims 15-18, 21-24 and 37 are, drawn to a polypeptide or protein of Chlamydia protein, classified in class 530, subclass 300.

III. Claims 20 and 25, drawn to antibodies, classified in class 424, subclass 164.1

IV. Claims 26-28, drawn to a method of treating infection with a nucleic acid molecule, classified in class 514, subclass 2 or 44.

V. Claims 29, 34 drawn to a method of treating infection with a protein or polypeptide molecule, classified in class 424, subclass 263.1.

VI. Claims 30 drawn to a method of treating infection with an antibody that binds to a Chlamydia protein or polypeptide molecule, classified in class 424, subclass 150.1.

VII. Claim 31 is, drawn to a method of detecting Chlamydia infection using a nucleic acid, classified in class 435, subclass 6.

VIII. Claim 32 is, drawn to a method of detecting diagnostic antibodies that bind to a Chlamydia polypeptide or protein, classified in class 435, subclass 7.36.

IX. Claim 33 is, drawn to a method of detecting a polypeptide or protein utilizing an antibody directed to a Chlamydia polypeptide or protein, classified in class 435, subclass 7.1.

2. The inventions are distinct, each from the other because of the following reasons:

3. Inventions I and II are related as apparatus and product made. The inventions in this relationship are distinct if either or both of the following can be shown: (1) that the apparatus as

claimed is not an obvious apparatus for making the product and the apparatus can be used for making a different product or (2) that the product as claimed can be made by another and materially different apparatus (MPEP § 806.05(g)). In this case that the product as claimed can be made by another and materially different apparatus, wherein the protein of Group II, may be obtained biosynthetic means or purified from naturally occurring sources, as well as using the polynucleotide for the production of a recombinantly expressed protein.

4. Inventions I and either one of Groups IV or VII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product as claimed can be used in a materially different process of using that product, wherein the DNA of Group I may be used in a method of transforming a host cell for the recombinant expression of antigen, in methods of detecting infection as well as the instant method of stimulating an immune response.

5. Inventions II and either one of Groups V or VIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product as claimed can be used in a materially different process of using that product, wherein the protein or polypeptide of Group II

may be used in the production of antibodies, the detection of antibodies, the purification of antibodies as well as in methods of preventing and treating infection.

6. Inventions III and either one of Groups VI or IX are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product as claimed can be used in a materially different process of using that product, wherein the antibodies may used in methods of treating infection, detecting antigen, for the induction of anti-idiotype antibodies and in methods of purifying antigen.

7. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

8. This application contains claims directed to the following patentably distinct species of the claimed invention:

9. Species for Group I:

(1) SEQ ID No 1 and 2;

(claims 1-2(a), 7, 8 (no optional second nucleic acid vector), 10, 12);

(2) a NA **fragment** of SEQ ID No 1 or encodes a fragment of SEQ 2; (claims 1-2 (b), 7, 8 (no optional second nucleic acid vector)), 10, 12 13-14, in so far as the claims DO Not recite an anti-sense fragment of SEQ ID No 1);

(3) a NA which is 75% identical SEQ ID No 1 or encodes SEQ ID NO 2 (claims 1-2 (c ), 7, 8 (no optional second nucleic acid vector), 10, 12;

(4) a NA **fragment** which is 75% identical a sequence of SEQ ID No 1 or a sequence that encodes a fragment amino acid sequence of SEQ ID NO 2 (claims 1-2 (c ), 7, 8 (no optional second nucleic acid vector), 10, 12, 13-14 in so far as the claims DO Not recite an anti-sense fragment of SEQ ID No 1;;

(5) an antisense NA for any one of species 1-4 listed above (claim 3, 13-14, in so far as the claims are directed to an anti-sense fragment of SEQ ID No 1);

(6) a nucleic acid molecule that encodes any one of the species of 1-4 listed above fused to a coding sequence for an additional polypeptide, signal peptide or adjuvant polypeptide (claims 4-6, 8-9, 11 ( optional second nucleic acid fusion vector)).

Species for Group II: A polypeptide with the amino acid sequence of

i. SEQ ID No 2, claim 15 (a);

ii. A polypeptide immunogenic **fragment** of at least 12 consecutive amino acids of SEQ 2 , claim 15(b);

iii. a polypeptide **fragment** which is 75% identical SEQ ID No 2 with modified immunogenicity, claim 15 ( subsection (c ) dependent upon claim subsection 15 (a));

iv. a polypeptide which is 75% identical SEQ ID No 2 with modified immunogenicity, claim 15 ( subsection (c ) dependent upon claim subsection 15 (b));

v. a fusion polypeptide that comprises any one of the species of I-iv listed above fused to an additional polypeptide, signal peptide or adjuvant polypeptide (claims 16-18)

Species for Group III: Antibodies that bind to a polypeptide with the amino acid sequence of

(1) SEQ ID No 2, claim 15 (a);

(2)A polypeptide immunogenic **fragment** of at least 12 consecutive amino acids of SEQ 2 , claim 15(b);

(3) a polypeptide **fragment** which is 75% identical SEQ ID No 2 with modified immunogenicity, claim 15 ( subsection (c ) dependent upon claim subsection 15 (a));

(4) a polypeptide which is 75% identical SEQ ID No 2 with modified immunogenicity, claim 15 ( subsection (c ) dependent upon claim subsection 15 (b));

Species for Group IV: A method of treating utilizing a nucleic acid of :

(a) SEQ ID No 1 and 2;

(b) a NA **fragment** of SEQ ID 1 or encodes a fragment of SEQ 2;

(c) a NA 75% identical to the coding sequence of SEQ ID NO 2;

(d) a NA **fragment** 75% identical to the coding sequence of SEQ ID NO 2

(e) a nucleic acid molecule that encodes any one of the species of (a )-(d) above fused to a coding sequence for an additional polypeptide, signal peptide or adjuvant polypeptide.

Species for Group V: A method of treating using polypeptide with the amino acid sequence of

(i) SEQ ID No 2, claim 15 (a);

(ii) A polypeptide immunogenic **fragment** of at least 12 consecutive amino acids of SEQ 2 , claim 15(b);

(iii) a polypeptide **fragment** which is 75% identical SEQ ID No 2 with modified immunogenicity, claim 15 ( subsection (c ) dependent upon claim subsection 15 (a));

(iv) a polypeptide which is 75% identical SEQ ID No 2 with modified immunogenicity, claim 15 ( subsection (c ) dependent upon claim subsection 15 (b));

Species for Group VI: A method of treating using an antibody that binds to a polypeptide with the amino acid sequence of :

1) SEQ ID No 2, claim 15 (a);

2) A polypeptide immunogenic **fragment** of at least 12 consecutive amino acids of SEQ 2 , claim 15(b);

3) a polypeptide **fragment** which is 75% identical SEQ ID No 2 with modified immunogenicity, claim 15 ( subsection (c ) dependent upon claim subsection 15 (a));

4) a polypeptide which is 75% identical SEQ ID No 2 with modified immunogenicity, claim 15 ( subsection (c ) dependent upon claim subsection 15 (b));

Species for Group VII: A method of detecting infection utilizing a nucleic acid of :

I) SEQ ID No 1 and 2;

II) a NA **fragment** of SEQ ID 1 or encodes a fragment of SEQ 2;

III) a NA 75% identical to the coding sequence of SEQ ID NO 2;

IV) a NA **fragment** 75% identical to the coding sequence of SEQ ID NO 2

Species for Group VIII: A method of detecting infection using polypeptide with the amino acid sequence of

a. SEQ ID No 2, claim 15 (a);

b. A polypeptide immunogenic **fragment** of at least 12 consecutive amino acids of SEQ 2 , claim 15(b);

c. a polypeptide **fragment** which is 75% identical SEQ ID No 2 with modified immunogenicity, claim 15 ( subsection (c ) dependent upon claim subsection 15 (a));

d. a polypeptide which is 75% identical SEQ ID No 2 with modified immunogenicity, claim 15 ( subsection (c ) dependent upon claim subsection 15 (b));

Species for Group XI: A method of detecting infection using an antibody that binds to a polypeptide with the amino acid sequence of :

1) SEQ ID No 2, claim 15 (a);

2) A polypeptide immunogenic **fragment** of at least 12 consecutive amino acids of SEQ 2 , claim 15(b);

3) a polypeptide **fragment** which is 75% identical SEQ ID No 2 with modified immunogenicity, claim 15 ( subsection (c ) dependent upon claim subsection 15 (a));

4) a polypeptide which is 75% identical SEQ ID No 2 with modified immunogenicity, claim 15 ( subsection (c ) dependent upon claim subsection 15 (b));

10. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

Currently, no claims are generic for Group I, Group II, Group III, Group IV, Group V, Group VI, Group VII, Group VIII, or Group IX.

11. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

12. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

13. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

14. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

15. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently

named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

16.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ginny Portner whose telephone number is (703)308-7543. The examiner can normally be reached on Monday through Friday from 7:30 AM to 5:00 PM except for the first Friday of each two week period.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached on (703) 308-3909. The fax phone number for this group is (703) 308-4242.

The Group and/or Art Unit location of your application in the PTO will be Group Art Unit 1645. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to this Art Unit.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Vgp
June 26, 2002

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